POSTER

Complete drainage of the pericardial fluid is performed, with the fluid sent for analysis and cytology. The guidewire is reintroduced, and the pigtail exchanged for an 8Fr 23cm Arrow braided sheath. Contrast injection confirms intrapericardial location. A 7fr Cordis BiPal biopsy forceps is passed through the sheath and away from the cardiac shadow to the lateral pericardial wall. A total of five biopsy specimens are obtained. Finally, the guidewire is re-introduced, the sheath is withdrawn, and the pigtail catheter is reintroduced.
Results: A total of 7 cases have been performed. The mean age is 60.5 +/- 8 years. Male-female ratio is 3:4 respectively. Mean WCC on presentation is 9.1 +/- 4.1. Mean ESR is 41 +/- 31.
Three had documented fever with one having flu-like symptoms.In four cases, biopsy was performed to out-rule malignant involvement of the pericardium in cancer patients presenting with symptomatic pericardial effusions. In three cases, biopsy was performed to aid diagnosis of recurrent idiopathic pericardial effusions.The biopsy in combination with cytology out-ruled malignant invasion in the four cases of malignancy. In the recurrent pericardial effusions, it confirmed the presence of lymphocytic pericarditis in one case, and organizing effusive pericarditis in two.
Conclusions: Percutaneous Pericardial biopsy is technically feasible and can be performed safely in order to assist in diagnosis of underlying pericardial disease.

Valvular Heart Disease - Aortic

(Abstract Nos 478-503)

TCT-478

Real-Time MRI-Guided Transarterial Aortic Valve Implantation: In Vivo Evaluation in Swine

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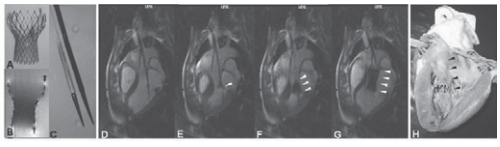
Background: MRI is considered an attractive alternative for guiding transarterial aortic valve implantation (TAVI), potentially overcoming inherent shortcomings of X-ray and angiography. Beyond mitigation of radiation exposure and nephrotoxic contrast media, MRI provides an unlimited scan plane orientation and unsurpassed soft-tissue contrast with simultaneous device visualization, thereby permitting safe device navigation through the vasculature and, importantly, precise orientation for axial positioning during valve deployment.
Methods: On the basis of a comprehensive in vitro analysis of both commercial TAVI devices regarding MR compatibility, the nitinol-based, self-expandable CoreValve prosthesis (Medtronic, USA), providing artifact-free and detailled visualization by MRI (A,B), was chosen for this study. The commercial delivery catheter required significant modifications prior MRI application, obviating any ferromagnetic braiding which would compromize MR safety and imaging quality. TAVI was performed in 8 swine via femoral (n=2) and subclavian (n=6) artery access on a 1.5T MRI scanner.
Results: Real-time MRI using TrueFISP imaging sequences permitted safe device navigation through the vasculature and precise steering during passage of the native aortic valve (D) and during placement and stepwise release of the stent-valve within the annulus (E-G). Post-interventional therapeutic success could be confirmed using ECG-triggered cine-TrueFISP sequences as well as flow-sensitive phase contrast sequences revealing or excluding regurgitation, respectively. Correct valve position was confirmed by ex vivo histology (H).



Conclusions: Our study shows that the commercially available CoreValve prosthesis is suited for real-time MRI-guided TAVI after design modifications of the delivery system laying the groundwork.

TCT-479

A Rapidly Exchangeable Bioprosthetic Valve

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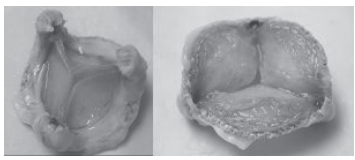
A Rapidly Exchangeable Bioprosthetic Valve.
Background: The trend towards using bioprosthetic valves in younger patients has improved quality of life but will lead to increased redo surgery for valve failure. Revalving failed valves with TAVI cannot be used routinely because of diminished EOA and durability concerns.
Methods: To address these issues, a rapidly exchangeable tissue valve has been developed. The design incorporates (i) flexible stent posts, (ii) well controlled central gap, and (iii) precise stent circularity with 120 degree leaflet symmetry - the three tenets of durable tissue valve design that have been demonstrated clinically. It is a two-component valve consisting of a permanent *"docking station"* and an *"exchangeable leaflet set"*. Three variants of the docking station are currently in development and testing. The surgical docking station has been tested in animals, a transapically implantable version is being tested, and a transfemoral implant is in development. All versions use the same, transapically exchangeable leaflet set.
Results: We have implanted 18 such valves into adolescent sheep and exchanged 7 after 3 months of implant. Two sheep had a 2nd exchange 5 months after the 1st leaflet exchange. Fibrotic overgrowth was severe, as expected, and far greater in sheep than seen in humans (see figure). All leaflet sets were successfully surgically exchanged without any subsequent perivalvular leaks. Exchange time was about 2 minutes.



Conclusions: An off-pump, rapidly exchangeable valve thus has the potential to bring tissue valve quality-of-life to younger valve patients. Fibrosis can be managed with the appropriate tools, even when very severe as in the hyperfibrotic sheep model. The design features of the exchangeable valve will ensure longevity equivalent to surgical valves, yet enable non-surgical delivery and leaflet exchange.

TCT-480

The Role of Balloon Aortic Valvuloplasty in the Management of High Risk Patients with Aortic Stenosis

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Introduction: Transcatheter aortic valve intervention (TAVI) has identified a group of high risk patients not previously candidates for therapy (operative risk measured by STS score > 10% and/or co-morbid conditions). The role of balloon aortic valvuloplasty (BAV) in the management of these patients remains unclear. Described is the success of BAV as a tool to "bridge" patients waiting for definitive treatment: aortic valve replacement (AVR), TAVI, or trial-assigned medical management (MM).
Methods: From a population of 788 patients with critical aortic stenosis evaluated between 1/2006 and 2/2010 in our High Risk Aortic Valve Clinic, 152 patients (mean age = 81 ± 8.3 years) received BAV. Indications included surgical candidates whose surgery was delayed due to other procedures, co-morbidities or TAVI trial time constraints (Group Operable). Group Inoperable consisted of 85 patients deemed to be inoperable at the time of BAV treated with the specific goal of improving them to candidacy for AVR/TAVI. Patients offered BAV as palliative therapy only comprised Group Palliation.
Result: Patients of each cohort are presented in Table. 91.1% (41/45) of patients in Group Operable were bridged to or still await definitive therapy.

	Operable (n=45)	Inoperable (n=85)	Palliation (n=22)
STS PROM	10.6 ± 3.6	11.5 ± 6.4	12.5 ± 6.6
Patients bridged to definitive therapy	64.4 % (29/45)	35.3% (30/85)	22.7% (5/22)
# days till bridged to definitive therapy	101 ± 89.9	62.0 ± 40.7	126.2 ± 98.3
Kaplan-Meier Survival: 30 day	95.0	85.2	81.8
Kaplan-Meier Survival: 180 day	83.5	63.7	40.9
Kaplan-Meier Survival: 1 year	83.5	43.0	40.9
Kaplan-Meier Survival: 2 years	83.5	35.9	n/a
Overall Mortality	8.9%	30.6%	45.4%

Conclusions: In operable patients, BAV is an effective bridge to definitive therapy with an 8.9% overall mortality. BAV successfully improved over 1/3 of inoperable patients so that they could receive surgery or TAVI. Five palliative-only patients were converted to operative.

TCT-481

Silent Cerebral Ischemia After Transfemoral Aortic Valve Implantation: a Diffusion-Weighted Magnetic Resonance Imaging Study

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Background. After Transcatheter Aortic Valve Implantation (TAVI) stoke has been reported in up to 10% of patients. Moreover, silent cerebral ischemia was recently reported in up to 84% of cases after transfemoral TAVI. This has been ascribed mainly due to dislodgement and embolization of debris from aortic arch atheroma or from the calcified valve. We assessed the incidence of cerebral ischemia after transfemoral TAVI.
Methods. Twenty-nine patients were enrolled; TAVI procedures were performed by percutaneous approach, using the self-expanding III generation CoreValve device (Medtronic, Minneapolis, Minnesota USA) or the Edwards SAPIEN™ prosthesis (Edwards Lifesciences Inc, Irvine CA. USA). All patients underwent cerebral Diffusion-Weighted Magnetic Resonance Imaging (DW-MRI) before the procedure, and 3 days after TAVI. Neurological status was assessed using National Institute of Health Stroke Scale (NIHSS) either before and after procedure, as well as at 1-month follow-up.
Results. Among the 29 patients included in the study (26 treated by the self-expandable CoreVave Revalving system; 3 by the balloon-expandable Edwards SAPIEN™ prosthesis) , 20 patients (68.9%) presented chronic cerebral lesions at baseline MRI, none with neurological impairment. All TAVI procedures were successful. Seventeen patients (58.6%) underwent post-procedure DW-MRI, and 4 of them (23.5%) showed new ischemic lesions after TAVI. These lesions were mostly multiple and dispersed in both hemispheres in a pattern suggesting cerebral embolization. The remaining 12 patients did not undergo post-procedure MRI because of urgent needing of pace-maker implantation. No measurable impairments of neurocognitive function nor neurological events occurred during the in-hospital period, nor at 1-month follow-up.
Conclusions. The occurrence of new cerebral embolic lesions detected by DW-MRI is high in patients who underwent TAVI by femoral route. However these lesions were clinically silent.